Food and Drug Administration, HHS

§ 524.1465 Mupirocin.

- (a) Specifications. Each gram of ointment contains 20 milligrams mupirocin.
- (b) Sponsors. See Nos. 025463, 026637, 051672, and 054771 in \$510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Apply twice daily. Treatment should not exceed 30 days.
- (2) *Indications for use.* For the topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *S. intermedius*.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 18119, Apr. 11, 2007, as amended at 75 FR 79296, Dec. 20, 2010; 78 FR 52854, Aug. 27, 2013; 79 FR 10970, Feb. 27, 2014]

§ 524.1484 Neomycin ophthalmic and topical dosage forms.

§ 524.1484b Neomycin, isoflupredone, tetracaine, and myristyl-gammapicolinium powder.

- (a) Specifications. The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 1 milligram of isoflupredone acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.
- (b) Sponsor. See No. 054771 in \$510.600(c) of this chapter.
- (c) Conditions of use in horses, dogs, and cats—(1) Amount. Apply to affected areas as a dusting powder.
- (2) Indications for use. For the treatment or as adjunctive therapy of certain ear and skin conditions caused by or associated with neomycin-susceptible organisms and/or allergy; as a superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable; as a dusting powder following amputation of tails, claws, and dewclaws and following ear trimming, castrating, and surgical procedures as ovariohysterectomies. For the treatment of acute otitis externa, acute

moist dermatitis, and interdigital dermatitis in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978; 79 FR 10970, Feb. 27, 2014]

§ 524.1484c Neomycin, isoflupredone, and tetracaine ointment.

- (a) Specifications. The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.
- (b) Sponsor. See No. 054771 in \$510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.
- (2) Indications for use. For the treatment of acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978; 79 FR 10970, Feb. 27, 2014]

§ 524.1484d Neomycin, hydrocortisone, and tetracaine otic ointment.

(a) Specifications. The product contains 5 milligrams of neomycin sulfate,